

PRIA Fee Category Table - Biopesticides Division - New Products

Table 13.

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products" \l "footnote1"]	FY'17 & FY'18 Registrati on Service Fee (\$)
[HYPERLINK "http://www2.epa.gov/pria-fees/b652-pria-fee-category"]	124	New product; registered source of active ingredient; requires petition to amend established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply [HYPERLINK	13	12,764

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		"http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products" \l "footnote2"] ⁽³⁾		
[HYPERLINK "http://www2.epa.gov/pria-fees/b660-pria-fee-category"]	125	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. For microbial pesticides, the active ingredient(s) must not be re-isolated. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-	4	1,278

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		new-products" \\ "footnote2"] ⁽³⁾		
[HYPERLINK "http://www2.epa.gov/ pria-fees/b670-pria-fee- category"]	126	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. [HYPERLINK "http://www2.epa.gov/ pria-fees/pria-fee- category-table- biopesticides-division- new-products" \\ "footnote2"] ⁽³⁾	7	5,107

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[HYPERLINK "http://www2.epa.gov/pria-fees/b671-pria-fee-category"]	127	New product; unregistered source of active ingredient(s); requires a petition to amend an established tolerance or tolerance exemption; requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products" \l "footnote2"] ⁽³⁾	17	12,764

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[HYPERLINK "http://www2.epa.gov/pria-fees/b672-pria-fee-category"]	128	New product; unregistered source of active ingredient(s); non-food use or food use requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products" \l "footnote2"] ⁽³⁾	13	9,118
[HYPERLINK "http://www2.epa.gov/	129	New product MUP/EP; unregistered	10	5,107

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pria-fees/b673-pria-fee-category"]		source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products" \l "footnote2"] ⁽³⁾		
[HYPERLINK "http://www2.epa.gov/pria-fees/b674-pria-fee-category"]	130	New product MUP; Repack of identical registered end-use product as a manufacturing-use product; same registered uses only [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products" \l "footnote2"] ⁽³⁾	4	1,278
[HYPERLINK "http://www2.epa.gov/pria-fees/b675-pria-fee-category"]	131	New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only. [10	9,118

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		HYPERLINK "http://www2.epa.gov/ pria-fees/pria-fee- category-table- biopesticides-division- new-products" \l "footnote2"] ⁽³⁾		
[HYPERLINK "http://www2.epa.gov/ pria-fees/b676-pria-fee- category"]	132	New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry data must be submitted; requires: 1) submission of product specific data, and 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data	13	9,118

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		requirement does not apply. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products" \l "footnote2"] ⁽²⁾		
[HYPERLINK "http://www2.epa.gov/pria-fees/b677-pria-fee-category"]	133	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or animal safety studies and/or child resistant packaging [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products" \l "footnote2"] ⁽²⁾	10	8,820

¹A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

²An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

³Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.